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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,683	07/16/2001	Jamie M. Grooms	197319US/222962US	4376

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EXAMINER	
SNOW, BRUCE EDWARD	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/905,683	GROOMS ET AL.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *111-128* is/are pending in the application.

4a) Of the above claim(s) *119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *111-118 and 120-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed April 18, 2005, have been fully considered. Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools), applicant notes that the Examiner is specifically referring to the subparts of Figure 3 which is correct, however, as stated in the rejections "refer to all figures". Applicant argues that Albee fails to teach an "assembled implant suitable for implantation into a patient". As shown in at least sub Figures 10, 11, and 12 of Figure 3, first and second cortical bone portions can be assembled via retention pins. It is the Examiner's position that such a surgery in vivo fulfills claim language "assembled bone implant as a unitary body" found in the body of the claim. Regarding the language "suitable for implantation into a patient" found in the preamble, it is not clear if that limitation breathes any life or meaning into the claim; all claim elements of Albee are implanted. Additionally, it is conceivable that an assembled first and second cortical bone portion via a retention pin could be implanted into a second patient via a donor surgery fulfilling all functional language. Secondly, in situations of multiple brakes, it is conceivable that bone portions are connected together outside of the body and than placed back, such as skull fractures. Specifically referring to sub figure 15, it is unclear if the elements being secured together are bone, however, clearly teaches that more than one pin of appropriate diameter can be used.

Regarding the limitation "diameter", this does not limit the pin to a cylindrical shape.

Applicant's argument regarding sub-Figures 11-12 not teaching a "superimposed" (as claimed in claim 126) is persuasive and the rejection of claims 126-128 has been withdrawn.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030), applicant argues that Siebels teaches connecting (stacking) implant portions because it is easier to manufacture. In response to applicant's argument, the fact that Siebels recognized another advantage of their invention does not take away from the teaching and advantage of multiple portions stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289), applicant's arguments are not persuasive. **Coates specifically states that the implant of Brantigan is flawed because the materials used (including metals) of Brantigan are too stiff which causes stress shielding, etc., as stated in the grounds of rejection. Coates in the very next paragraph teaches bone as an implant material "avoid[s] the disadvantages of metal implants"; see column 2, lines 49 et seq.**

Double Patenting

All claims are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of all claims of copending Application No. 10/375,540. This is a

provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 111-118, 120-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools).

Referring to all figures, specifically figures 10-12 and 15, Albee teaches:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body.

Regarding figures 11-12, Albee teaches superimposed first and second cortical bone portions each have a D-shape having a through hole with receives the I shaped pin interpreted as having an appropriate diameter. Albee teaches the pines are grafts which inherently comprise cortical and cancellous bone.

Regarding claim 116, mirror image, see at least figure 15.

Regarding claim 121, the embodiments shown in figures 11-12 are sized and shaped for in the form of a cervical implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111-118 and 120-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030).

Referring to all figures, Coates teaches a D-shaped cortical bone spinal implant (see column 11, lines 42 et seq.). However, Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin. Siebels also teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding at least claims 114-115, 123, and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Seibels produce no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claim 122, see column 11, lines 62 et seq.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Claims 111-118 and 120-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289).

Referring to all figures, specifically figures 2 and 5, Brantigan teaches a D-shaped bone implant comprising:

a first portion 21;

a second portion 21;

said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body.

However, Brantigan fails to teach the first and second portions are cortical bone. Brantigan teaches the device can be made of traditional orthopaedic implant materials; see the abstract. Coates et al teaches a D shaped implant can be made of cortical bone. It would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopaedic implant material as taught by Coates for any of the elements of Brantigan because "*5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.*" See column 2, lines 40 et seq. of Coates.

Regarding at least claims 114-115, 123, and 127, the combination at least teaches titanium or cortical bone, lacking any criticality in the specification, the use of the specific use of any claimed materials for the pin in lieu of those taught by references produces no advantage and is considered an obvious matter of design choice.

Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

BRUCE SNOW
PRIMARY EXAMINER